IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
Civil Action No. 7:08-CV-00130-FL

VICTOR BROWN AND MARTHA BROWN, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	)	NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF OMNIBUS MOTION IN LIMINE

Novartis Pharmaceuticals Corporation ("NPC") submits this memorandum in support of its omnibus motion *in limine* to exclude the following:

1. Out-of-court statements by members of a panel of physicians and oral surgeons who provided comments regarding NPC's draft White Paper on the development of ONJ in patients using Zometa® and Aredia®.[1] – The statements include criticisms of portions of the White Paper, particularly its listing of risk factors other than bisphosphonate ("BP") use that might be associated with osteonecrosis of the jaw ("ONJ").[2] In prior Zometa® trials, plaintiffs have sought to introduce portions of these criticisms – such as the suggestion by Dr. Mark Schubert, an oral surgeon – that listing other risk factors was akin to "blowing smoke" and advising NPC to restrain itself from doing that in favor of "tak[ing] a bold and honest approach." Fussman Closing Arg. at 11:17-21, 12:7-10, 13:14-16 (Ex. 3). The rule against hearsay bars the admission of these statements because none of the healthcare professionals whose emails are at issue was

[1] *See* White Paper (Ex. 1).

[2] *See, e.g.*, May 12, 2004 Email from Dr. Mark Schubert, ZAEM00860680-81; May 28, 2004 Email from Mark Schubert, ZAEM001784506-08; May 12, 2004 Email from Ana Hoff, ZAEM00860748-49. (Ex. 2).

an employee, agent, or representative of NPC at the time of the statements, nor is there any evidence suggesting that these independent practitioners were authorized to make such statements on NPC's behalf. Fed. R. Evid. 801, 802; *see, e.g.*, *Dora Homes, Inc. v. Epperson*, 344 F. Supp. 2d 875, 883-85 (E.D.N.Y. 2004) ("admission of a party opponent" exception to hearsay rule inapplicable to statement made by independent contractors without a showing that defendant exercised control over them or authorized them to make statements on its behalf); *Mueller v. County of Westchester*, 943 F. Supp. 357, 359 n.2 (S.D.N.Y. 1996) (same), *aff'd*, No. 96-9487, 1997 U.S. App. LEXIS 23051 (2d Cir. 1997).

2. Testimony from Dr. Noopur Raje, a medical doctor with no NPC affiliation, including a videotaped presentation that Dr. Raje gave in September 2005 at a meeting of the American Association of Oral and Maxillofacial Surgeons ("AAOMS"). – In that AAOMS presentation, Dr. Raje discussed how she thought NPC identified potential cases of ONJ in its clinical trials. *See* 7/18/08 Deposition of Dr. Noopur Raje 130:2-131:5 (excerpts attached as Ex. 4). She speculated that NPC's report to FDA's Oncologic Drug Advisory Committee in 2005 likely underrepresented the incidence of ONJ in the clinical trials. *See id.* at 80:16-84:2. Plaintiffs cannot establish that Dr. Raje had personal knowledge of the issues at the time that she made the presentation to AAOMS. *See United States v. Garcia*, 291 F.3d 127, 140 (2d Cir. 2002); Fed. R. Evid. 602. She was not involved in NPC's clinical trials and did not participate in NPC's review of its clinical trial data. Raje Dep. at 163:24-164:22. Additionally, the speculations of Dr. Raje and the videotape are not admissible because they are pure hearsay. Fed. R. Evid. 802. These portions of the deposition, including the playing of the videotape, were excluded in a recent Zometa® trial. *See Fussman v. Novartis Pharms. Corp.*, 1:06-CV-149, Tr. Trans. at 106-13 (M.D.N.C. Nov. 1, 2010) (Ex. 5).

3. "Recommendations from the Osteonecrosis of the Jaw (ONJ) Advisory Panel," 16-Mar. 2005 ("Recommendations") (Ex. 6). – The Advisory Panel was the "Zoledronic Acid Bone Clinical Development Group," a group discussing the development of what was later named Reclast®, *i.e.*, zoledronic acid for benign indications such as Paget's Disease. (Zometa®, in contrast, is indicated for treatment of cancer patients, *not* benign indications.) *See* 3/9/05 Hua email, ZAEM-001386728-29 ("The purpose of the meeting is to develop strategies to mitigate ONJ risks in zoledronic acid *benign indications*.") (emphasis added) (Ex. 7). The participants discussed how the labeling for NPC's new medication should differ from the labeling of Zometa® on the issue of listing other risk factors for ONJ. *See* Recommendations at 7 (Ex. 6). In one of the Zometa® trials, the plaintiff argued that the document actually recommended removal of such risk factors *from the Zometa® label itself*. Fussman Closing Arg. at 8:1-7 (Ex. 3). However, the "proposed US package insert" at issue at the meeting was not the *Zometa*® label but the proposed label for Reclast®. *See* Hua email. Although Zometa® shares the same active ingredient as Reclast®, the conditions for which the two drugs are prescribed are vastly different. Significantly, cancer patients given Zometa® are known to receive a plethora of other drugs such as chemotherapy, steroids, thalidomide, etc., that are uncommon in the patients to whom Reclast® would be prescribed. A label for Reclast® would not need to identify the identical other risk factors for ONJ that were included on the Zometa® label. Accordingly, the recommendations for the Reclast® label are irrelevant to the adequacy of the Zometa® label. Fed. R. Evid. 401-03.

4. A statement made by Dr. Jack Gotcher at the annual AAOMS meeting in September, 2005. – On September 21-24, 2005, during a symposium at the AAOMS annual meeting, Dr. Gotcher, an oral surgeon, addressed a panel discussing ONJ. Specifically, he remarked:

> I did a study with W S S Jee and it was published in 1981 in the Journal of Perio Research where we looked at experimental periodontal disease in the rice rat and we gave clodronate as a bisphosphonate and we were able to produce osteonecrosis at the high dose which were 10 milligrams per kg day given over a long period of time. So that was in the literature back in 1981.

See Fussman v. Novartis Pharms. Corp., No. 1:06-cv-00149 (M.D.N.C. Nov. 17, 2010), Trial Tr. at 132:14-21 (Ex. 8). In one of the most recent Zometa® trials, the plaintiff elicited this hearsay statement to corroborate his position that long before beginning to market Zometa®, NPC should have known from this animal study about the possibility that BP drugs could cause ONJ . Fussman Closing Argument at 6:8-17 (Ex. 3). Plaintiffs in this case should not be permitted to do the same as this statement is inadmissible hearsay. Fed. R. Evid. 802.

5. Sales and marketing materials that were neither seen nor relied upon by Plaintiff Victor Brown or his prescribing physicians. – To the extent that Plaintiffs cannot establish that Plaintiff Victor Brown ("Mr. Brown") or his prescribing physicians ever saw NPC sales or marketing materials or any advertisements regarding Zometa®, any such proffered evidence would be irrelevant. *See In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, at *4-5 (M.D. Fla. Jan 30, 2009) (in the absence of exposure to the prescribing physician, promotional material must be excluded) (Ex. 9); *see also In re Norplant Contraceptive Prods. Liab. Litig.* No. MDL 1038, 1997 WL 81092, at *1 (E.D. Tex. Feb. 21, 1997) (excluding internal marketing and promotional materials because, "[a]bsent evidence that the physicians were exposed to [such materials]," they are not relevant) (Ex. 10).

6. Testimony or evidence that NPC misled, deceived, or defrauded FDA about Zometa®. – NPC expects that Plaintiffs may seek to introduce evidence or offer testimony that NPC misled, deceived, defrauded, or provided inadequate information to U.S. Food and Drug Administration ("FDA") about Zometa®. Any such evidence or testimony is inadmissible. *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 353 (2001) (holding that the Food, Drug, and Cosmetic Act ("FDCA") preempts state law claims of fraud on FDA). FDA is solely responsible for examining a drug manufacturer's disclosures of adverse events and investigating suspected instances of fraud or misrepresentations by a manufacturer. 21 U.S.C. § 372. The Supreme Court in *Buckman* held that Congress permits only FDA to punish and deter violations of its disclosure requirements. *Buckman* 531 U.S. at 348. Citizens can only report suspected wrongdoing and petition FDA to take action against a drug manufacturer. 21 C.F.R. § 10.30.

Plaintiffs' expert witnesses claim that NPC withheld information or fraudulently misled FDA, and then speculate as to what FDA would have done differently if it had received the allegedly withheld information.[3] Numerous courts have held that *Buckman* precludes not only specific claims that a manufacturer defrauded FDA, but also admission of such evidence in support of common law tort claims. *See, e.g., Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 n.3 (4th Cir. 2001) ("[Plaintiff] contends that to prevail on his state-law 'fraud-on-the-FDA' claim, he needs only to show that 'but for' [Defendant's] fraud on the FDA, he never would have

[3] For example, Plaintiffs' regulatory expert, Dr. Suzanne Parisian, makes numerous statements about the alleged inadequacy of NPC's disclosures. *See, e.g.*, Expert Report of Dr. Suzanne Parisian (Oct. 6, 2008) ¶ 78 (NPC was "not forthcoming" in its interactions with FDA); ¶ 95 (NPC convened an expert advisory board meeting "under the guise of science . . . to present facts to the panel members that were not true in light of what Novartis knew"); ¶ 111 (NPC engaged in a "strategy" to "manipulate[] what little information it . . . provide[d]" to FDA in order to discredit the data it provided); ¶ 175 (NPC "marginaliz[ed] the reporting of ONJ"); and ¶ 195 (arguing that NPC placed profits over patient safety) ("Parisian Report") (filed under seal at Dkt. No. 53).

been injured . . . . As result [of *Buckman*], [Plaintiff's] fraud-on-the-FDA claim must be dismissed."); *Fitzgerald v. Smith & Nephew, Inc.*, 11 F. App'x 335, 339 n.3 (4th Cir. 2001) (noting that during oral argument, "Plaintiff rightly acknowledged that the recent decision of the Supreme Court of the United States in [*Buckman*] precludes her claims of fraud on, and related to, the FDA" and concluding that, "[h]ence, the causation argument respecting those claims is moot and we do not further consider it"); *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (explaining that "plaintiffs cannot bootstrap their arguments regarding defendant's alleged failure to report and to investigate adverse incidents to the FDA into a defective warning case"); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008) (finding while plaintiff had not alleged defendant committed fraud on FDA, "her argument that [defendant] failed to disclose all relevant information to the agency essentially equates to that" and "[u]nder *Buckman*, then, she cannot prevail"); *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) ("Evidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA."); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776-77 (D. Minn. 2009) ("[A] private litigant cannot sue a defendant for violating the FDCA. Similarly, a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA . . . ."); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 WL 2374742, at *10 (N.D. Cal. Aug. 16, 2006) (citing *Buckman* and holding that "[t]he law is well established that a claim premised on a drug manufacturer's failure to provide data to the FDA is preempted") (Ex. 11).

Because Plaintiffs may not assert state-law claims based upon the alleged inadequacy of information provided to FDA, any evidence or argument that NPC concealed scientific data or

provided insufficient submissions, or speculation about what the agency would have done with different information, is irrelevant and should be excluded. Under *Buckman*, any argument that NPC's communications or submissions were not timely, not complete, or could have included different or "better" information - or speculation about how the agency would have responded to different information - is irrelevant and inadmissible because the sufficiency of submissions to FDA is to be judged solely by FDA, not juries addressing the law of fifty states.

Further, Federal Rule of Evidence 403 precludes Plaintiffs from referencing NPC's purported inadequate or misleading communications with FDA because the probative value of this information "is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Introducing this evidence would lengthen the trial by requiring NPC to defend against these collateral allegations. Moreover, presenting such information at trial would be highly prejudicial to NPC and would create the risk that the jury may impose liability on NPC for the allegedly insufficient disclosures to FDA rather than for allegedly failing to provide an adequate warning to Mr. Brown's treating physician, which is the duty actually at issue in this case. What FDA *may* have done, if anything, with different data and how that information *may* have ultimately affected Zometa®'s regulatory status, if at all, is precisely the type of speculation that *Buckman* prohibits, and permitting such evidence would waste the time of the Court and confuse the jury with standards that are not only irrelevant in this case but consideration of which is preempted.

7. Miscellaneous.

a. Testimony or evidence that some or many of the articles concerning BPs in medical journals were actually "ghostwritten" by drug companies, including NPC. – *See* Expert Report of

Dr. Suzanne Parisian (Oct. 6, 2008) ¶ 232 ("Parisian Report") (filed under seal at Dkt. No. 53); *In re Seroquel Prods. Liab. Litig.*, 2009 WL 223140, at *3 ("To the extent that [the defendant pharmaceutical company] seeks to preclude Plaintiff's use of the terms 'ghostwriting' or 'plagiarism' the Motion to Exclude is granted.") (Ex. 9).

b. Evidence concerning foreign regulatory actions or materials such as package inserts for Zometa® distributed in foreign countries. – NPC expects Plaintiffs to seek to introduce evidence concerning foreign regulatory actions or materials such as package inserts distributed in foreign countries. Foreign package inserts and other materials are regulated by each foreign country's separate regulatory authority, just as the United States package insert is regulated by the FDA. NPC operates only in the United States and thus is not responsible for labeling or regulatory decisions abroad.[4] In addition, there is no evidence that Mr. Brown's prescribing physicians ever read any foreign package insert or was exposed to any foreign regulatory materials of any sort.

Any differences in package inserts from country to country are the result of separate regulatory processes having nothing to do with each other and reflect laws and regulations specific to each country. Any such evidence would be unhelpful and confusing to the jury and would be prejudicial to NPC, which would have to take precious time to explain the relevant foreign regulatory context. Furthermore, no witness has testified that any foreign package insert for Zometa® contains a stronger or earlier warning than that in the United States, or that any foreign regulatory document or action is relevant in any way to NPC's liability in this case.

c. Discovery disputes. – Any such disputes are irrelevant to the issues before the jury, may tend to prejudice NPC in the eyes of the jury, and will likely confuse the jury. Fed. R. Evid. 401-03.

[4] None of NPC's parents or affiliated corporations is a defendant in this action.

d. Characterizations of counsel for NPC in a manner that could prejudice NPC. – Objectionable references would include, without limitation, references to where NPC's counsel's law firms are located and where NPC's counsel reside, the areas of practice of NPC's counsel or their law firms, and the identity of NPC's counsel's other clients, including the size of those clients and the nature of their businesses. Fed. R. Evid. 401-03.

e. Reference to Drug Companies Having an "Incestuous" Relationship with FDA. – NPC anticipates that Plaintiffs' counsel or experts may assert or otherwise imply to the jury that NPC and the FDA have a special relationship of some kind and may characterize that relationship as "incestuous" in an inappropriate effort to influence the jury to the prejudice of NPC. *See* Boles Trial Tr. at 1669:9-15, 1682:1-3 and 1686:2-6; *Boles v. Merck & Co.*, 06-cv-9455 (JFK) (S.D.N.Y. June 24, 2010) (wherein counsel for a plaintiff in an oral bisphosphonate case repeatedly stated in closing argument that the defendant pharmaceutical company and FDA had an "incestuous" relationship) (Ex. 12). Such references have no basis in fact, are irrelevant to the issues before the jury, and excludable under the Federal Rules of Evidence. *See* Fed. R. Evid. 401 and 403. Accordingly, NPC requests that the Court issue an order precluding Plaintiffs, Plaintiffs' witnesses, and Plaintiffs' counsel from referring to a relationship of any kind between NPC and FDA.

f. References to Dr. Suzanne Parisian as the "Former Chief Medical Officer" of FDA. – NPC anticipates Plaintiffs' counsel will refer to Plaintiffs' expert, Dr. Suzanne Parisian, as the "former chief medical officer" of FDA. *See* Maley Trial Tr. at 24:14-15, *Louise H. Maley v. Merck & Co.*, 06-CV-4110 (JFK) (S.D.N.Y. April 19, 2010) (wherein counsel for a plaintiff in an oral bisphosphonate case called Dr. Parisian "the former chief medical officer of the FDA") (excerpts attached as Ex. 13). Dr. Parisian has never been *the* chief medical officer of FDA, but

was *a* chief medical officer - one of many. The Court should prohibit Plaintiffs' counsel from claiming Dr. Parisian held such a position, which will not be provable during trial, in an attempt to exaggerate her experience and impress the jury, resulting in undue prejudice to NPC. *See* Fed. R. Evid. 403.

g. Reference to Dental Pain Jurors May Have Experienced and the Treatment They Received. – NPC anticipates that Plaintiffs' counsel may ask jurors, when evaluating Plaintiffs' case, to consider their own experiences with dental pain and the treatments they have received. Counsel for a plaintiff in a case involving an oral bisphosphonate recently made a similar request of the jury. *See Maley* Trial Tr. at 13:1-4 ("I'm sure all of you have had some dental pain at one time or another. Whether you had an impacted molar or cavity and you had pain in your jaw. And it was pretty miserable . . .") (Ex. 13). The Court should prohibit Plaintiffs' counsel from asking the jury to relate Plaintiffs' situation to their own lives because such requests are unduly prejudicial to NPC. *See* Fed. R. Evid. 403.

h. Evidence Regarding "Moral Obligations" and "Legal Conclusions" by Plaintiffs' Experts. – NPC anticipates that Plaintiffs' experts may attempt to express opinions as to alleged "moral obligations" that NPC has or had to Plaintiffs or the general public. While Plaintiffs' experts may or may not be qualified to testify with respect to medical or regulatory issues, there can be little doubt that they are not qualified to testify regarding any "moral obligations" of NPC. Moreover, no cause of action in Plaintiffs' Second Amended Complaint alleges that NPC failed to fulfill any "moral obligation" to Plaintiffs. Accordingly, Plaintiffs' experts should be prohibited from opining or implying that NPC had any "moral obligation" to Plaintiffs or the general public or that any such obligation was breached or otherwise unfulfilled. *See* Fed. R. Evid. 702 (limiting expert testimony to "scientific, technical, or other specialized knowledge").

NPC also anticipates that Plaintiffs' experts may attempt to invade the province of the Court and testify regarding conclusions of law. Expert opinions that go no further than providing the expert's view of the law do not "assist the trier of fact" and thus should be excluded under Rule 702 of the Federal Rules of Evidence. *See Woods v. Lecureux*, 110 F.3d 1215, 1220 (6th Cir. 1997) (noting that "it is . . . apparent that testimony offering nothing more than a legal conclusion - i.e., testimony that does little more than tell the jury what result to reach - is properly excludable under the Rules.").

i. Evidence or Argument Regarding Regulatory Enforcement or Interactions Between FDA and NPC Concerning Drugs Other Than Aredia® or Zometa®. – NPC expects that Plaintiffs will offer evidence concerning FDA or other regulatory enforcement relating to NPC drugs other than Aredia® or Zometa®, or interactions between FDA and NPC concerning other drugs. Regulation of NPC drugs not at issue in this action is irrelevant and unduly prejudicial under Federal Rules of Evidence 401 and 403. In particular, FDA letters regarding *other* NPC products have nothing to do with issues in the case at bar. There is no evidence relating to any of NPC's other drugs that has any bearing on Plaintiffs' case. Such evidence would also be unduly prejudicial, would confuse and mislead the jury as to the differences or similarities between the other drugs and Aredia® and Zometa®, and the presentation of evidence on such matters would waste valuable trial time. *See* Fed. R. Evid. 401 and 403 (stating that "undue delay" and "waste of time" are bases upon which to exclude evidence).

j. References to Testimony by Plaintiffs' Expert, Dr. Robert E. Marx, Regarding His Compensation. – NPC understands that one of Plaintiffs' experts, Dr. Robert E. Marx, may testify that he is not being compensated for the time he spends working on Plaintiffs' case. *See* Transcript of the 12/8/09 Deposition of Dr. Robert Marx at 190:16-192:6 (hereafter "12/8/09

Marx Dep.") ("Once again, I am not paid, my salary does not increase for my participation in this, nor do I receive any bonus related to this.") (excerpt attached as Ex. 14). This testimony tends to give the impression that Plaintiffs' counsel is not compensating anyone for Dr. Marx's work on this matter and that Dr. Marx is working for free in service to the plaintiffs who he claims was harmed by NPC. In fact, Dr. Marx's employer, the University of Miami, is being compensated for his work on Plaintiffs' case. *See* 12/8/09 Marx Dep. at 191:12-18 ("Q. When you say that you are an unpaid expert witness, that just refers to what you have testified before in the sense that the billing and the funds that are charged for your time go to your department as opposed to directly to you right? A. Well, they go to the university. Does that affect my department indirectly? Yes.") (Ex. 14).[5] In light thereof, NPC respectfully requests that the Court preclude Dr. Marx from testifying that he is not being compensated for his work in this matter.

k. Reference to NPC's Corporate Structure or to the Fact that NPC Is Based in Switzerland. – NPC's parent company, Novartis International AG, is a multinational pharmaceutical company based in Basel, Switzerland. NPC expects that Plaintiffs' counsel or Plaintiffs' experts may refer to the corporate structure of NPC or NPC's parent company to encourage the jury to adopt a "David v. Goliath" view of this action, thereby prejudicing NPC in the eyes of the jury and preventing NPC from being afforded the chance to present its defense to an impartial jury. Further, NPC anticipates that Plaintiffs' counsel or Plaintiffs' experts may refer to the fact that NPC's parent company is based in Switzerland to take advantage of any anti-foreign or otherwise xenophobic sentiments that may be present within the jury. Where

[5] Over the course of this litigation, NPC has paid at least $67,610.25 to the University of Miami in compensation for the time spent by Dr. Marx for depositions requested by NPC. These payments are in addition to the payments the University of Miami has received from Plaintiffs' counsel.

NPC's parent company is located and how NPC is structured have no bearing on the issues the jury will be faced with deciding and any references to these matters should be precluded pursuant to Rules 401 and 403 of the Federal Rules of Evidence.

CONCLUSION

For the foregoing reasons, NPC requests that the Court preclude discussion of the issues addressed herein by Plaintiffs, their witnesses, or their counsel at any time in front of the jury, including but not limited to during *voir dire*.

Dated: December 2, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF OMNIBUS MOTION IN LIMINE, using the CM/ECF system, which will send notification of such filing to CM/ECF participants:

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This the 2nd day of December, 2011.

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